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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,858	07/27/2001	Mark C. Shults	1146-4DIV/CIP 2	1611

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/916,858	<b>Applicant(s)</b> SHULTS ET AL	
	<b>Examiner</b> Robert L. Nasser	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/21/2004</u> | 6) <input type="checkbox"/> Other: _____  |

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Before applying art, the examiner notes that to the best of the examiner's understanding, the term "composite" membrane means a membrane having two contiguous layers.

In addition, the examiner notes that based on this interpretation, it is the examiner's opinion that claims 1-3, 7-12, 15-17, 20, 22, 23, and 25-34 find support in the parent applications, 09/447227 and 08/811473, and therefore are entitled to the filing date of March 4, 1997.

However, it is the examiner's position that claims 4-6, 13, 14, 18, 19, 21, 35-43 do not find support in the parent applications, and therefore have the filing date of this application, or July 27, 2001.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-23, 25-34, 42, and 43 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33-42, 48, 49, and 54-87 of copending Application No. 09/447227. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader versions of the patented claims, , and, as such, are covered by the pending claims. . The examiner notes with respect to claims 3-10, 42 and 43, applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem. Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use. As to the device claims, the method covers providing the device. Hence, it covers the device.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-23, 25-34, 42, and 43 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-320 US Patent 6,741,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader than some of the pending claims, and as such are covered by the pending claims. The examiner notes with respect to claims 3-10, 42 and 43, applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem. Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use. As to the method claims, it

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would have been obvious to use the device of the patented claims for the current method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 18, 19, 22, 23, 25-34, and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al WO 92/13271 in view of Picha. Rhodes shows an implantable glucose sensing device having a housing containing internal electrodes, and a three layer membrane, where in the third layer is an interference layer (see page 7 bottom – page 8 top) which provide a controlled volume to the electrodes, second layer is a enzyme membrane see page 7, and the first layer is a bioprotective layer. The device does not have an angiogenic layer. However, Picha teaches that using an angiogenic layer surrounding an implantable sensor improves the accuracy of the implantable sensor. Hence, it would have been obvious to modify Rhodes et al to use the angiogenic layer, so as to improve the overall accuracy of the device. As such, the angiogenic layer on the bioprotective membrane 12 are a composite membrane. Claims 3-10, 42, and 43 are rejected in that Rhodes teaches all of the materials for the membranes (see discussion begging on page 19) except the PTFE. However, applicant has not stated that the particular materials used for the layers are for a specific purpose or that the materials used solve a stated problem.

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Indeed, applicant notes that many materials may be used for each of the layers. As such, it would have been a mere matter of design choice for one skilled in the art to select the proper materials for use. Claim 19 is rejected in that Rhodes teaches the recited materials. Claims 22 and 23 are rejected in that Rhodes teaches a wireless transmitter (see page 19, line 6). The exact type of transmitter would have been a mere matter of design choice for one skilled in the art. With respect to claim 25, the combination teaches the method except for the length of implantation. However, it is the examiner's position that the addition of the angiogenic layer would enable sensing for long periods including the recited period. Claims 26-31 are rejected in that Rhodes shows the method.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al et al in view Picha, as applied to claims 1-12, 18, 19, 22, 23, 25-34, and 42-43 above, further in view of Van Antwerp et al. Van Antwerp et al shows a device for measuring glucose that uses an optical absorbance sensor rather than an electrochemical sensor. Hence, it would have been obvious to modify the above combination to use such an absorbance sensor, as it is merely the substitution of one known sensor for another.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al et al in view Picha, as applied to claims 1-12, 18, 19, 22, 23, 25-34, and 42-43 above, further in view of Blubaugh Jr. et al. Blubaugh further teaches a pore size for the bioprotective layer in the claimed range. Hence, it would have been obvious

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to modify Rhodes et al to use such a pore size, as it is merely the substitution of one known membrane structure for another.

Claims 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al in view Picha, as applied to claims 1-12, 18, 19, 22, 23, 25-34, and 42-43 above, further in view of Ceramic. Ceramic shows an alternate glucose sensor that uses a concanavalin A as a reverse binding agent for glucose. Hence, it would have been obvious to modify the above combination to use the sensor arrangement of Cerami, as it is merely the substitution of one known equivalent for another.

Claims 13, 14, 20, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 13 and 14 define over the art of record in that none of the art shows a metal film on the side of the interference layer distal to the sensor. Claims 20 and 21 define over the art in that none of the art shows an angiogenic layer and a material for securing the device to biological tissue, as claimed.

Applicant's arguments filed 6/21/2004 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
9/20/2004



ROBERT L. NASSER  
PRIMARY EXAMINER